K100744

Date:	October 5, 2010
Subject:	510(k) Summary of Safety and Effectiveness Information for the NeuWave Medical Certus 140 2.45 GHz Ablation System and Accessories
Company:	NeuWave Medical, Inc. 3529 Anderson Street Madison, WI 53704
FDA Establishment#	TBD
Contact:	Dan Kosednar, Director of Regulatory Affairs and Quality Assurance P – 608-512-1592 F – 608-512-1509
Proprietary:	Certus 140 2.45 GHz Ablation System and Accessories
Common:	System, Ablation, Microwave and Accessories
Classification:	General and Plastic Surgery, 73 NEY, 21 CFR 878.4440

OCT 2 2 2010

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

Predicate Devices

The Certus 140 2.45 GHz Ablation System and Accessories is substantially equivalent to the following currently marketed device:

- ValleyLab Microwave Ablation Generator - Class II - 21CFR878.4400, which has been the subject of a cleared 510(k) with FDA log number 072687 and K053535.
- ValleyLab Cool-Tip RF Generator, Cool-Tip RF System and Accessories - Class II - 21CFR878.4400, which has been the subject of a cleared 510(k) with FDA log number K052796 and K053290.
- EndoCare CryoCare Surgical System, Model Cryo 20 - Class II - 21CFR878.4350, which has been the subject of a cleared 510(k) with FDA log number K023757.
- Microsurgeon Microwave Tissue Ablation Device - Class II - 21CFR878.4400, which has been the subject of a cleared 510(k) with FDA log number 070023
- Boston Scientific RF 3000Generator - Class II - 21CFR878.4400, which has been the subject of a cleared 510(k) with FDA log number K000241

Intended Use

The NeuWave Medical Certus 140 2.45 GHz Ablation System and Accessories are intended for the ablation (coagulation) of soft tissue.

The Certus 140 2.45 GHz Ablation System is not intended for use in cardiac procedures.

NeuWave recommends against the use of the Certus 140 2.45 GHz Ablation System in the following situations:

- Pregnant patients – potential risks to patient and/or fetus have not been established
- Patients with implantable pacemakers or other electronic implants. Implanted electronic devices may be adversely affected by microwave power

The system is designed for facility use and should only be used under the orders of a clinician.

Device Description

The system has three (3) independent 2.45 GHz microwave generators, each capable of producing up to 140W each. One, easy to use, touch-screen user interface controls the system. Up to 3 microwave ablation probes can be connected to and powered by the system at one time. The maximum selectable power for the system is 140W when one probe is connected, 95Wper probe when 2 probes are connected and 65W per probe when 3 probes are connected. An intermediate junction box or Power Distribution Module (PDM) reduces system set up complexity.

Probes are provided sterile and are intended for single patient use only. Probes are available for both percutaeous and open surgical applications. Percutaneous probes are comprised of 17 gauge needles, a probe handle, a 1.4M cable and a connector assembly. Percutaneous probes are available in Certus ^{LK} and Certus ^{LN}. Certus ^{LK} probes are designed to perform optimally, in terms of efficiently transferring energy into tissue, in liver and kidney tissue. Certus 140^{LN} probes are designed to perform optimally, in terms of efficiently transferring energy into tissue, in lung tissue. All percutaeous probes are available in 15cm and 20 cm lengths.

The open surgical probe, Certus ^{SR}, is 13 gauge and available in a 25cm length.

All probes have temperature sensing thermocouples at various places along the shaft to monitor the probe temperature.

A CO_2 based cooling system ensures the non-active portion of the probe does not exceed temperature requirements. Additionally, the CO_2 enables the Tissu-Loc function, which can be used to adhere or stick the probe in place prior to starting ablation therapy. This function is similar in use to the stick function available on cryogenic ablation systems.

The system uses two (2) E-sized CO_2 cylinders. When a tank in use empties, the system will automatically switch to using the other tank and notify the user to replace the empty tank.

Performance Data

The Certus 140 2.45 GHz Ablation System and Accessories has been designed to comply with the applicable portions of various International Standards, including:

- UL 60601-1:2003
- IEC 60601-1:1988 Plus Amendments
- IEC 60601-2-2:2006
- IEC 60601-2-6:1984
- IEC 60601-1-2:2007
- EN ISO 11607-1:2006

- ISO 10993-1: 2003

The Certus 140 2.45 GHz Ablation System and Accessories and the predicate devices are substantially equivalent in design concepts, technologies and materials. The Certus 140 Ablation 2.45 GHz System and Accessories has been verified through rigorous testing that, in part, supports the compliance of Certus 140 2.45 GHz Ablation System and Accessories to the standards listed above.

Ex-vivo studies were conducted to compare the performance of the Certus 140 2.45 GHz Ablation System and Accessories to a predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NeuWave Medical, Inc.
% Mr. Daniel Kosednar
3529 Anderson Street
Madison, Wisconsin 53704

OCT 2 2 2010

Re: K100744
Trade Name: Certus 140 2.45 GHz Ablation System and Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY, GEI
Dated: October 6, 2010
Received: October 7, 2010

Dear Mr. Kosednar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

K100744

OCT 2 2 2010

510(k) Number (if known): K

Device Name: Certus 140 2.45 GHz Ablation System and Accessories

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Prescription Use _XXX_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100744